

HB 2796

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# WEST VIRGINIA LEGISLATURE

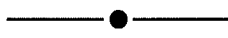
FIRST REGULAR SESSION, 1999



# ENROLLED

## House Bill No. 2796

(By Delegates Border, Leach and Perdue (By Request))



Passed March 11, 1999

In Effect Ninety Days from Passage

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OFFICE OF WEST VIRGINIA  
SECRETARY OF STATE

**ENROLLED**  
**H. B. 2796**

(BY DELEGATES BORDER, LEACH AND PERDUE (BY REQUEST))

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[Passed March 11, 1999; in effect ninety days from passage.]

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AN ACT to amend and reenact sections six-a, nine and fourteen, article five, chapter thirty of the code of West Virginia, one thousand nine hundred thirty-one, as amended; to further amend said article by adding thereto a new section, designated section nine-a; and to amend and reenact section seven, article eight, chapter sixty-a of said code, all relating to fees for licensing and permits to operate for pharmacists, pharmacies, drugstores and wholesale drug distributors payable to the West Virginia Board of Pharmacy; establishing an initial fee and a renewal fee for an application for a permit for mail-order pharmacies and drugstores; increasing the renewal fees for licensing and operation permits for pharmacists; increasing the licensing fee for wholesale drug distributors; and authorizing future fee modifications to be made by legislative rule.

*Be it enacted by the Legislature of West Virginia:*

That sections six-a, nine and fourteen, article five, chapter thirty of the code of West Virginia, one thousand nine hundred thirty-one, as amended, be amended and reenacted; that said article be further amended by adding thereto a new section, designated section nine-a; and that section seven, article eight, chapter sixty-a of said code be amended and reenacted, all to read as follows:

**CHAPTER 30. PROFESSIONS AND OCCUPATIONS.****ARTICLE 5. PHARMACISTS, PHARMACY TECHNICIANS, PHARMACY  
INTERNS AND PHARMACIES.****§30-5-6a. Permits for mail-order houses.**

1 (a) Every mail-order house which dispenses drugs or  
2 medicines through the United States mail or otherwise from any  
3 point in the state of West Virginia to any point outside of the  
4 state of West Virginia shall be registered as a pharmacy or  
5 drugstore pursuant to the provisions of section fourteen of this  
6 article: *Provided*, That the provisions of this subsection do not  
7 apply to any mail-order house which operates solely as a  
8 wholesale distributor. Every initial application for a permit shall  
9 be accompanied by a fee of five hundred dollars. The fee for  
10 renewal of the permit or license shall be five hundred dollars  
11 annually.

12 (b) Every mail-order house which dispenses drugs or  
13 medicines through the United States mail or otherwise from any  
14 point outside of the state of West Virginia to any point within  
15 the state of West Virginia shall, as a condition precedent to  
16 being qualified and authorized to transact business in the state  
17 of West Virginia, annually register with the board of pharmacy  
18 to conduct such business in this state. Every initial application  
19 for a permit shall be accompanied by a fee of five hundred  
20 dollars. The fee for renewal of the permit or license shall be  
21 five hundred dollars annually. Every business shall be required  
22 to provide to the board of pharmacy satisfactory evidence that  
23 it qualifies as a pharmacy or drugstore and that the business is  
24 licensed or registered as a pharmacy or drugstore in the state  
25 where the business dispenses prescriptions by mail order to  
26 residents of this state. The board of pharmacy shall promulgate  
27 rules, in accordance with the provisions of article three, chapter  
28 twenty-nine-a of this code, for the procedures of registration  
29 pursuant to this subsection: *Provided*, That the provisions of  
30 this subsection do not apply to any mail-order house which  
31 operates solely as a wholesale distributor.

**§30-5-9. Fees.**

1 The board of pharmacy shall charge and collect the  
2 following fees, in addition to those provided in article one of  
3 this chapter and in sections five, fourteen and sixteen of this  
4 article: For renewing the licensure of a pharmacist, fifty dollars;  
5 to license an intern pharmacist, ten dollars plus five dollars for  
6 each of the remaining periods of his or her internship; to  
7 register a consultant pharmacist, twenty dollars for the initial  
8 application and ten dollars for each additional application; and  
9 to register a pharmacy technician, twenty-five dollars and ten  
10 dollars for each renewal.

**§30-5-9a. Authorization for future fee modifications to be made  
by rule.**

1 Notwithstanding any other provision of this code to the  
2 contrary, beginning on the first day of July, one thousand nine  
3 hundred ninety-nine, the board may set any fee authorized  
4 under this article by legislative rule, in accordance with article  
5 three, chapter twenty-nine-a of this code.

**§30-5-14. Pharmacies to be registered; permit to operate; fees;  
pharmacist to conduct business.**

1 (a) The board of pharmacy shall require and provide for the  
2 annual registration of every pharmacy doing business in this  
3 state. Any person, firm, corporation or partnership desiring to  
4 operate, maintain, open or establish a pharmacy in this state  
5 shall apply to the board of pharmacy for a permit to do so. The  
6 application for such permit shall be made on a form prescribed  
7 and furnished by the board of pharmacy, which, when properly  
8 executed, shall indicate the owner, manager, trustee, lessee,  
9 receiver, or other person or persons desiring such permit, as  
10 well as the location of such pharmacy, including street and  
11 number, and any other information as the board of pharmacy  
12 may require. If it is desired to operate, maintain, open or  
13 establish more than one pharmacy, separate application shall be  
14 made and separate permits or licenses shall be issued for each.

15 (b) Every initial application for a permit shall be accompa-  
16 nied by the required fee of one hundred fifty dollars. The fee for  
17 renewal of such permit or license shall be one hundred dollars  
18 annually.

19 (c) If an application is approved, the secretary of the board  
20 of pharmacy shall issue to the applicant a permit or license for  
21 each pharmacy for which application is made. Permits or  
22 licenses issued under this section shall not be transferable and  
23 shall expire on the thirtieth day of June of each calendar year,  
24 and if application for renewal of permit or license is not made  
25 on or before that date, or a new one granted on or before the  
26 first day of August, following, the old permit or license shall  
27 lapse and become null and void and shall require an inspection  
28 of the pharmacy and a fee of one hundred fifty dollars plus one  
29 hundred fifty dollars for the inspection.

30 (d) Every place of business so registered shall employ a  
31 pharmacist in charge and operate in compliance with the  
32 general provisions governing the practice of pharmacy and the  
33 operation of a pharmacy.

34 (e) The provisions of this section shall have no application  
35 to the sale of nonprescription drugs which are not required to be  
36 dispensed pursuant to a practitioner's prescription.

## **CHAPTER 60A. UNIFORM CONTROLLED SUBSTANCES ACT.**

### **ARTICLE 8. WHOLESALE DRUG DISTRIBUTION LICENSING ACT OF 1991.**

#### **§60A-8-7. Wholesale drug distributor licensing requirements.**

1 All wholesale distributors and pharmacy distributors shall  
2 be subject to the following requirements:

3 (a) No person or distribution outlet may act as a wholesale  
4 drug distributor without first obtaining a license to do so from  
5 the board of pharmacy and paying any reasonable fee required  
6 by the board of pharmacy, such fee not to exceed four hundred  
7 dollars per year.

8 (b) The board of pharmacy may grant a temporary license  
9 when a wholesale drug distributor first applies for a license to  
10 operate within this state and the temporary license shall remain  
11 valid until the board of pharmacy finds that the applicant meets  
12 or fails to meet the requirements for regular licensure, except

13 that no temporary license shall be valid for more than ninety  
14 days from the date of issuance. Any temporary license issued  
15 pursuant to this subdivision shall be renewable for a similar  
16 period of time not to exceed ninety days pursuant to policies  
17 and procedures to be prescribed by the board of pharmacy.

18 (c) No license may be issued or renewed for a wholesale  
19 drug distributor to operate unless the distributor operates in a  
20 manner prescribed by law and according to the rules promul-  
21 gated by the board of pharmacy with respect thereto.

22 (d) The board of pharmacy may require a separate license  
23 for each facility directly or indirectly owned or operated by the  
24 same business entity within this state, or for a parent entity with  
25 divisions, subsidiaries, or affiliate companies within this state  
26 when operations are conducted at more than one location and  
27 there exists joint ownership and control among all the entities.

28 (e) (1) As a condition for receiving and retaining any  
29 wholesale drug distributor license issued pursuant to this article,  
30 each applicant shall satisfy the board of pharmacy that it has  
31 and will continuously maintain:

32 (A) Acceptable storage and handling conditions plus  
33 facilities standards;

34 (B) Minimum liability and other insurance as may be  
35 required under any applicable federal or state law;

36 (C) A security system which includes after hours central  
37 alarm or comparable entry detection capability, restricted  
38 premises access, adequate outside perimeter lighting, compre-  
39 hensive employment applicant screening and safeguards against  
40 employee theft;

41 (D) An electronic, manual or any other reasonable system  
42 of records describing all wholesale distributor activities  
43 governed by this article for the two-year period following  
44 disposition of each product and being reasonably accessible as  
45 defined by board of pharmacy regulations during any inspection  
46 authorized by the board of pharmacy;

47 (E) Officers, directors, managers and other persons in  
48 charge of wholesale drug distribution, storage and handling,

49 who must at all times demonstrate and maintain their capability  
50 of conducting business according to sound financial practices  
51 as well as state and federal law;

52 (F) Complete, updated information to be provided the board  
53 of pharmacy as a condition for obtaining and retaining a license  
54 about each wholesale distributor to be licensed under this article  
55 including all pertinent licensee ownership and other key  
56 personnel and facilities information determined necessary for  
57 enforcement of this article, with any changes in the information  
58 to be submitted at the time of license renewal or within twelve  
59 months from the date of the change, whichever occurs first;

60 (G) Written policies and procedures which assure reason-  
61 able wholesale distributor preparation for protection against and  
62 handling of any facility security or operation problems,  
63 including, but not limited to, those caused by natural disaster or  
64 government emergency, inventory inaccuracies or product  
65 shipping and receiving, outdated product or other unauthorized  
66 product control, appropriate disposition of returned goods and  
67 product recalls;

68 (H) Sufficient inspection procedures for all incoming and  
69 outgoing product shipments; and

70 (I) Operations in compliance with all federal legal require-  
71 ments applicable to wholesale drug distribution.

72 (2) The board of pharmacy shall consider, at a minimum,  
73 the following factors in reviewing the qualifications of persons  
74 who engage in wholesale distribution of prescription drugs with  
75 this state:

76 (A) Any conviction of the applicant under any federal, state  
77 or local laws relating to drug samples, wholesale or retail drug  
78 distribution or distribution of controlled substances;

79 (B) Any felony convictions of the applicant under federal,  
80 state or local laws;

81 (C) The applicant's past experience in the manufacture or  
82 distribution of prescription drugs, including controlled sub-  
83 stances;

84 (D) The furnishing by the applicant of false or fraudulent  
85 material in any application made in connection with drug  
86 manufacturing or distribution;

87 (E) Suspension or revocation by federal, state or local  
88 government of any license currently or previously held by the  
89 applicant for the manufacture or distribution of any drug,  
90 including controlled substances;

91 (F) Compliance with licensing requirements under previ-  
92 ously granted licenses, if any;

93 (G) Compliance with requirements to maintain and make  
94 available to the board of pharmacy or to federal, state or local  
95 law-enforcement officials those records required by this article;  
96 and

97 (H) Any other factors or qualifications the board of  
98 pharmacy considers relevant to and consistent with the public  
99 health and safety, including whether the granting of the license  
100 would not be in the public interest.

101 (3) All requirements set forth in this subsection shall  
102 conform to wholesale drug distributor licensing guidelines  
103 formally adopted by the United States food and drug adminis-  
104 tration (FDA); and in case of conflict between any wholesale  
105 drug distributor licensing requirement imposed by the board of  
106 pharmacy pursuant to this subsection and any food and drug  
107 administration wholesale drug distributor licensing guideline,  
108 the latter shall control.

109 (f) An agent or employee of any licensed wholesale drug  
110 distributor need not seek licensure under this section and may  
111 lawfully possess pharmaceutical drugs when the agent or  
112 employee is acting in the usual course of business or employ-  
113 ment.

114 (g) The issuance of a license pursuant to this article does  
115 not change or affect tax liability imposed by this state's  
116 department of tax and revenue on any wholesale drug distribu-  
117 tor.

118 (h) The board of pharmacy may adopt rules pursuant to  
119 section nine of this article which permit out-of-state wholesale



120 drug distributors to obtain any license required by this article on  
121 the basis of reciprocity to the extent that: (i) An out-of-state  
122 wholesale drug distributor possesses a valid license granted by  
123 another state pursuant to legal standards comparable to those  
124 which must be met by a wholesale drug distributor of this state  
125 as prerequisites for obtaining a license under the laws of this  
126 state; and (ii) such other state would extend reciprocal treatment  
127 under its own laws to a wholesale drug distributor of this state.

That Joint Committee on Enrolled Bills hereby certifies that the foregoing bill is correctly enrolled.

*Paul Leponova*  
Chairman Senate Committee

*Joe F. Smith*  
Chairman House Committee

Originating in the House.

Takes effect ninety days from passage.

*Barrett Adams*  
Clerk of the Senate

*Suzanne M. Smith*  
Clerk of the House of Delegates

*Carl Ray Tomblin*  
President of the Senate

*[Signature]*  
Speaker of the House of Delegates

The within *approved* this the *27th*  
day of *March*, 1999.

*[Signature]*  
Governor

PRESENTED TO THE

GOVERNOR

Date 3/23/99

Time 4:00pm